

REMARKS

Applicants have received and carefully reviewed the Final Office Action mailed September 15, 2009. Currently, claims 16-20, 22-33, and 35-36 remain pending. Claims 16-20, 22-33, and 35-36 have been rejected. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections under 35 U.S.C. §103

On page 2 of the Final Office Action, claims 16-20, 22, 24, 29-33 and 35-36 were rejected under 35 U.S.C. §103(a) as being unpatentable over Webster, Jr. (U.S. Patent No. 5,057,092) in view of Kaye (U.S. Patent No. 4,191,219). After careful review, Applicants respectfully traverse this rejection.

Turning to claim 16, which recites:

16. An intravascular catheter comprising an elongate shaft including an inner polymer layer defining a lumen of the elongate shaft, a reinforcement layer disposed about the inner polymer layer, and an outer polymer layer disposed about the reinforcement layer, the reinforcement layer comprising a tubular braid having a first helical member interwoven with a second helical member forming a plurality of crossover points and a plurality of axial members disposed between the first helical member and the second helical member at each of the plurality of crossover points such that the lumen of the elongate shaft and an outer surface of the outer polymer layer are free from radial protrusions.

Nowhere do Webster, Jr. or Kaye disclose many elements of claim 16, including for example, “the reinforcement layer comprising a tubular braid having a first helical member interwoven with a second helical member forming a plurality of crossover points and a plurality of axial members disposed between the first helical member and the second helical member at each of the plurality of crossover points such that the lumen of the elongate shaft and an outer surface of the outer polymer layer are free from radial protrusions”.

Instead, Webster, Jr. discloses an intravascular catheter including an elongated catheter body having a flexible plastic inner wall 22, a braided reinforcing mesh 24 surrounding the inner wall 22, and a flexible plastic outer wall 30 surrounding the reinforcing mesh 24. The braided reinforcing mesh 24 includes a plurality of interwoven helical members 26. Webster, Jr. teaches that, typically, half of the interwoven helical members 26 extend in one direction and the other

half of interwoven helical members 26 extend in the counter direction. In addition, the braided reinforcing mesh 24 includes longitudinal warp members 28. However, the longitudinal warp members 28 are not disposed between the first and second helical members 26 at each of the plurality of crossover points. Instead, at numerous crossover points, both the first and second helical members 26 are on the same side of the longitudinal warp members 28. See, for example, Figure 2. As such, Webster, Jr. does not teach or suggest the longitudinal warp members 28 disposed between the first and second helical members at each of the plurality of crossover points.

Kaye discloses a triaxial fabric for use as a needlepoint canvas with the yarns forming the fabric being defined by three sets of yarn courses with the courses within each set being parallel. The courses of each set are angular to the courses of the other two sets, usually at a 60-degree angle with the courses from all three sets commonly intersecting at a plurality of points in a repetitive pattern over the fabric. (See Abstract). Applicants respectfully assert that fabric for a needlepoint canvas formed of yarn as taught by Kaye is clearly non-analogous art.

As the Examiner is aware, a *prima facie* case of obviousness is established "when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *Application of Rinehart*, 531 F.2d 1048, 1052 (CCPA, 1976). "The reference must either be in the field of the applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned" *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992). In *Application of Wood*, the court presumes, when determining obviousness, "full knowledge by the inventor of all the prior art in the field of his endeavor. However, with regard to prior art outside the field of his endeavor, we only presume knowledge from those arts reasonably pertinent to the particular problem with which the inventor was involved." 599 F.2d 1032, 1036 (CCPA, 1979).

Clearly, fabric for a needlepoint canvas is not in Applicants' field of endeavor. Applicants' field of endeavor, as evidenced by the Field of Invention on page 1 of the present application, is intravascular catheters or, more specifically, intravascular catheters having a braid reinforcement. As Kaye is not in Applicants' field of endeavor, it must be reasonably pertinent to the particular problem with which the inventor was involved. Applicants respectfully assert that yarn for a needlepoint fabric is clearly not reasonably pertinent to axial members for a

braided reinforcement layer disposed between an inner and outer polymer layer and that a person of skill in the art would not look to needlepoint fabric when designing medical devices. Thus, Applicants respectfully assert that Kaye is non-analogous art and cannot be relied upon to establish a *prima facie* case of obviousness.

However, if Kaye is somehow considered analogous art (which Applicants believe is not), Applicants respectfully assert that Webster, Jr. teaches away from any combination with Kaye. Applicants note that MPEP § 2141.02 states “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)”. Further, “[i]t is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)”. (MPEP § 2145). As noted above, Kaye discloses setting the angle of the threads (for example, D, E, F, G, H, I, J, K shown in Figures 2 and 3) at a 60-degree angle relative to the warp courses (for example, C shown in Figures 2 and 3) for the weave. However, column 2, lines 44-53 of Webster, Jr. states:

The tightness or angle of the helical members 26 to the longitudinal members 28 is not critical but is preferably from about 30° to about 45°. An angle less than about 30° is not preferred because as the braid angle becomes smaller, the catheter tends to buckle when it is bent. Further, such catheters tend not to transmit torque around corners as well as catheters having higher braid angles. Braid angles greater than 45° are not preferred because they do not appear to offer any advantage and are less economical.

(Emphasis added). From this, Webster Jr. teaches away from braid angles greater than 45 degrees. As such, one of skill in the art would not combine the weave pattern of Kaye having 60-degree angles with the teachings of Webster, Jr. that teaches patterns of 45 degrees or less. Thus, Applicants respectfully assert that Webster, Jr. teaches away from any combination with Kaye and, as such, the asserted combination is clearly improper.

Further, it is axiomatic that “because they can be” clearly fails to establish a proper *prima facie* case of obviousness. Under KSR, there must be some reason to make the claimed combination. The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) stated:

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory

statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”.

(Emphasis added) (see page 14 of the April 30, 2007 decision). The Court further stated:

a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

(see page 14 of the April 30, 2007 decision). It appears that the rejection has merely found several elements of the claim in the prior art and has made a conclusion of obviousness without any articulated reasoning with some rational underpinning to support the conclusion. The reasoning provided in the Final Office Action to support the legal conclusion of obviousness is that “it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Webster with an interwoven cross construction, as taught by Kaye, in order to prevent slippage, maximize tear resistance, high torsional stiffness, high resiliency and high flexibility”. However, these reasons appear to come directly from Applicants’ own specification, see for example, paragraphs 13, 36-41, and 47. Further, the Final Office Action also cites to page 13, lines 3-5 of Applicants’ specification for support. Applicants note MPEP § 2142 states:

Knowledge of applicant’s disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the “differences,” conduct the search and evaluate the “subject matter as a whole” of the invention. The tendency to resort to “hindsight” based upon applicant’s disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

Applicants submit that the only motivation or reason for combining Webster, Jr. and Kaye in the manner suggested by the Final Office Action comes from Applicants’ own specification, which is clearly improper.

The Final Office Action also suggests that “a plurality of axial members disposed between the first helical member and the second helical member at each of the plurality of crossover points” is an obvious design choice. Applicants respectfully disagree. Notably, the MPEP only discusses an obvious design choice with regards to rearrangement of parts. MPEP § 2144.04(VI)(C) states:

In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (Claims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device.); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice). However, “The mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims on appeal is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, without the benefit of appellant’s specification, to make the necessary changes in the reference device.” *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984).

(Emphasis added). As can be seen, “the mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims ... is not by itself sufficient to support a finding of obviousness”, but that the prior art must provide a motivation or reason for the rearrangement. Applicants respectfully assert that “a plurality of axial members disposed between the first helical member and the second helical member at each of the plurality of crossover points” is not an obvious matter of design choice or a mere rearrangement of parts, as suggested in the Final Office Action. As is readily apparent from the present specification, “a plurality of axial members disposed between the first helical member and the second helical member at each of the plurality of crossover points” may indeed modify the operation of the intravascular catheter, and may provide additional benefits over the system disclosed by Webster, Jr. For example, the claimed intravascular catheter may help maintain low friction and adequate sealing of the catheter. Further, as noted above, nothing in Webster, Jr. provides any reason or motivation, without the benefit of Applicants’ specification, to make the necessary changes to the device of Webster, Jr. Therefore, for at least these reasons, claim 16 is believed to be patentable over Webster, Jr. and Kaye. For similar reasons and others, claims 17-20, 22 and 24, which depend from claim 16 and which include additional distinguishing features, are believed to be patentable over Webster, Jr. and Kaye.

Applicants note that page 3 of the Final Office Action states, “it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. ‘for the entire length of the axial member’, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference...”.

Applicants note that nowhere do any of the claims recite “for the entire length of the axial member”.

Turning to claim 29, which recites:

29. A method of making a portion of a shaft of an intravascular catheter, the method comprising the steps of:

providing a carrier including an elongate tube having an inner polymer layer disposed thereon;

braiding a first helical member and a second helical member about the carrier forming a plurality of crossover points such that a plurality of axial members are disposed between the first and second helical members at each of the plurality of crossover points to form a reinforcement layer that is free of radial protrusions; and

disposing an outer polymer layer over the reinforcement layer.

Nowhere do Webster, Jr. and Kaye disclose many elements of claim 29, including for example, the specific method step of “braiding a first helical member and a second helical member about the carrier forming a plurality of crossover points such that a plurality of axial members are disposed between the first and second helical members at each of the plurality of crossover points to form a reinforcement layer that is free of radial protrusions”. Therefore, for similar reasons discussed above, as well as others, claim 29 is believed to be patentable over Webster, Jr. and Kaye. For similar reasons and others, claims 30-32, which depend from claim 29 and which include additional distinguishing features, are believed to be patentable over Webster Jr. and Kaye.

Turning to claim 33, which recites:

33. An intravascular catheter comprising an elongate shaft having an inner polymer layer, a reinforcement layer disposed about the inner polymer layer, and an outer polymer layer disposed about the reinforcement layer, the reinforcement layer comprising a tubular braid having a first helical member interwoven with a second helical member forming a plurality of crossover points and one or more axially extending members disposed between the first helical member and the second helical member so that the reinforcement layer is free of crossover points having the first helical member and the second helical member both inside of the one or more axially extending members or both outside of the one or more axially extending members such that the reinforcement layer is free of radial protrusions caused by the one or more axial members.

Nowhere do Webster, Jr. and Kaye disclose many elements of claim 33, including for example, the specific method step of “the reinforcement layer comprising a tubular braid having a first

helical member interwoven with a second helical member forming a plurality of crossover points and one or more axially extending members disposed between the first helical member and the second helical member so that the reinforcement layer is free of crossover points having the first helical member and the second helical member both inside of the one or more axially extending members or both outside of the one or more axially extending members such that the reinforcement layer is free of radial protrusions caused by the one or more axial members". Therefore, for similar reasons discussed above, as well as others, claim 33 is believed to be patentable over Webster, Jr. and Kaye. For similar reasons and others, claims 35-36, which depend from claim 33 and which include additional distinguishing features, are believed to be patentable over Webster Jr. and Kaye.

On page 5 of the Final Office Action, claims 16-20, 22, 24, 29-33, 35 and 36 were rejected under 35 U.S.C. §103(a) as being unpatentable over Webster (U.S. Patent No. 5,057,092) in view of Huppert (U.S. Patent No. 2,114,274). After careful review, Applicants respectfully traverse this rejection.

As discussed above, a *prima facie* case of obviousness is established "when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *Application of Rinehart*, 531 F.2d 1048, 1052 (CCPA, 1976). "The reference must either be in the field of the applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned" *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992). Huppert discloses a tubular braid for use in the manufacture of hair dressing accessories, such as foundations, curlers, rollers, and the like. Clearly, a tubular braid for hair dressing accessories is not in Applicants' field of endeavor, which, as evidenced by the Field of Invention on page 1 of the present application, is intravascular. Further, Applicants respectfully assert that hair dressing accessories are not reasonably pertinent to axial members for a braided reinforcement layer disposed between an inner and outer polymer layer and that a person of skill in the art would not look to hair dressing accessories when designing medical devices. Thus, Applicants respectfully assert that Huppert is non-analogous art and cannot be relied upon to establish a *prima facie* case of obviousness.

The Final Office Action asserts that "Huppert discloses a tubular braid for use among other purpose. In this case, a medical article such as a catheter thus is analogous in structure to

tubular braid of Huppert. Therefore, the braid tubular and the catheter tube are interchangeable and can be used in catheter arts as it relates with the tubular”. Applicants disagree. As discussed above, Huppert discloses a tubular braid for hair dressing accessories, such as foundations, curlers, rollers, and the like. Clearly hair dressing accessories are not interchangeable with medical device catheters, as suggested in the Office Action. Medical device catheters are used for, for example, intravascular procedures, whereas hair dressing accessories are used generally for dressing hair. Clearly these are not interchangeable.

However, if Huppert is somehow considered analogous art (which Applicants believe is not), Applicants respectfully assert that Webster, Jr. and Huppert fail to disclose all the elements of claim 16, as admitted on page 6 of the Final Office Action, namely, “a plurality of axial members disposed between the first helical member and the second helical member at each of the plurality of crossover points”. The Final Office Action, however, asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to add more axial members for the purpose of increasing the reinforcing or torsional rigidity. This is not understood. Applicants can find no reason in Webster, Jr. or Huppert for adding more axial members to modify the device of Webster, Jr. to have “a plurality of axial members disposed between the first helical member and the second helical member at each of the plurality of crossover points”. In fact, the only reason appears to come from Applicants’ own specification, which is clearly improper.

Further, it is axiomatic that “because they can be” clearly fails to establish a proper *prima facie* case of obviousness. Under KSR, there must be some reason to make the claimed combination. The Supreme Court in *KSR Int’l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) stated:

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a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

(see page 14 of the April 30, 2007 Decision). The rejection has merely found several elements of the claim in the prior art and has made a conclusion of obviousness without any articulated reasoning with some rational underpinning to support the conclusion. The reasoning provided in the Final Office Action to support the legal conclusion of obviousness is that "it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Webster with an interwoven cross construction, as taught by Huppert, in order to prevent slippage, maximize tear resistance, high torsional stiffness, high resiliency and high flexibility". However, these reasons come directly from Applicants' own specification; see for example, paragraphs 13, 36-41, and 47. Applicants note MPEP § 2142 states:

Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

Applicants submit that the only motivation or reason for combining Webster, Jr. and Huppert in the manner suggested by the Final Office Action comes from Applicants' own specification, which is clearly improper. Therefore, for at least these reasons, claim 16 is believed to be patentable over Webster, Jr. and Huppert. For similar reasons and others, claims 17-20, 22 and 24, which depend from claim 16 and which include additional distinguishing features, are believed to be patentable over Webster, Jr. and Huppert.

For similar reasons and others, independent claims 29 and 33 are believed to be patentable over Webster, Jr. in view of Huppert. For similar reasons and others, claims 30-32 and 35-36, which depend from one of claim 29 or claim 33 and which include additional distinguishing features, are believed to be patentable over Webster, Jr. in view of Huppert.

On page 7 of the Final Office Action, claims 23 and 25-28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Webster, Jr. (U.S. Patent No. 5,057,092) in view of Kaye (U.S. Patent No. 4,191,219) or Huppert (U.S. Patent No. 2,114,274) and further in view of Mortier et al. (U.S. Patent No. 5,730,733). After careful review, Applicants respectfully traverse this rejection. As discussed previously, claim 16 is believed to be patentable over Webster, Jr. and Kaye or Huppert, and nothing in Mortier et al. remedies the above-noted shortcomings of

Webster, Jr. Therefore, for at least these reasons, claims 23 and 25-28, which depend from claim 16 and which include additional limitations, are believed to be patentable over the cited references.

Double Patenting Rejections

On page 8 of the Final Office Action, claims 16-32 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,709,429. Also on page 9 of the Final Office Action, claims 16 and 22-30 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6-9, 11 and 13-28 of U.S. Patent No. 6,942,654. Applicants do not concede the correctness of the rejection. However, if the rejection remains when the claims are otherwise indicated as being allowable, Applicants will file a Terminal Disclaimer.

Conclusion

Reconsideration and further examination of the rejections are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
Dean A. Schaefer et al.
By their Attorney,

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/david m. crompton/
David M. Crompton, Reg. No. 36,772
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, MN 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349